UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

Susan Rosen,

Plaintiff,

v.

St. Jude Medical, Inc.,
Pacesetter, Inc.,

Defendants.

No. 13-1159 (LEK/CFH)
Judge Lawrence E. Kahn

AMENDED COMPLAINT

Through the undersigned counsel, plaintiff Susan Rosen ("Plaintiff") brings this Amended Complaint against defendants St. Jude Medical, Inc., and Pacesetter, Inc. (collectively "St. Jude" or "Defendants"). On personal knowledge, and on investigation and the information and belief of her counsel, Plaintiff avers the following:

I. INTRODUCTION

1. Plaintiff brings this Complaint against Defendants for injuries caused by defects in her St. Jude Riata Lead (hereinafter "Riata Leads" or "Leads") and by violations of Defendants' state-law duty of care to report known risks with the use of the Leads. Plaintiff alleges that she was implanted with a defective Riata Lead and subsequently suffered injury as a result of these defects and violations.

2. St. Jude manufactures a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). Wires called Leads, are attached to the ICD, then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires via cables and conductors and are positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

3. In 1996, St. Jude received approval to market the Ventritex TVI. Lead, the predecessor of the Riata and Riata ST Leads. St. Jude Medical ultimately introduced its Riata Leads into the U.S. market beginning in 2002. These Leads were based on the original submission to the U.S. Food and Drug Administration ("FDA") in 1996 and numerous supplements. Approximately 227,000 Riata Leads have been sold worldwide since being approved for marketing. 79,000 Riata Leads are estimated to remain active in the United States.

4. Defendants soon realized that the Riata Leads were subject to higher than expected rates of insulation abrasion and commissioned an internal audit to investigate the abrasion issues, but did not disclose adequate information to the public regarding the increased risk of abrasion.

5. In late 2010, Defendants ceased marketing of the Riata Leads and issued a Dear Doctor letter on November 28, 2011.

6. On December 14, 2011 the FDA classified Defendants' November 2011 advisory as a Class I Recall. This Recall includes the following Riata Lead model numbers: Riata (8Fr): 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592; and Riata (7Fr): 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042.

II. PARTIES

A. Plaintiff

7. Plaintiff is a citizen and resident of Saratoga County in the State of New York.

8. Plaintiff was implanted with a Riata Lead in August 2004. On or around September 25, 2012, Plaintiff's treating professionals determined that the Lead was not operating properly and that the Lead may have fractured.

9. On or around October 8, 2012, Plaintiff's Riata Lead was surgically extracted. The surgeon found the Lead had fractured and the conductor coils had externalized.

10. As a result of the defect in her Riata Lead, Plaintiff has been injured and will continue to suffer physical, emotional, economic and other damage. Plaintiff's damages include but are not limited to extrusion of the conductor, compromised lead insulation, increased lead impedance, and electrical abnormalities in her Riata Lead resulting in invasive and dangerous surgery.

B. Defendants

11. Defendant St. Jude Medical, Inc. is a Minnesota corporation that is headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota.

12. Defendant St. Jude Medical manufactures medical devices that are sold in more than 100 countries around the world and had net sales of over $5.6 billion in 2011.

13. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principal place of business at 15900 Valley View Court, Sylmar, California. Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, develops, manufactures, and distributes cardiovascular and implantable neurostimulation medical devices, including the Riata and Riata ST Leads at issue here. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc. Prior to 1994, Pacesetter was known as Siemens Pacesetter, Inc.

14. Pacesetter also holds the trademark for Riata. Specifically, on September 7, 2001, Pacesetter filed a federal trademark registration. The United States Patent and Trademark Office (USPTO) issued the RIATA mark, Ser. No. 76310892, to Pacesetter on November 5, 2002. The correspondent listed for RIATA is Steven M. Mitchell of Pacesetter, Inc., 15900 Valley View Court, Sylmar, California. The RIATA trademark is filed in the category of Medical Instrument

Products. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

III. JURISDICTION AND VENUE

15. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy exceeds Seventy-Five Thousand Dollars ($75.000), exclusive of interest and costs.

16. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(a)(2) because Defendants regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenues from goods used in the State of New York.

IV. FACTUAL ALLEGATIONS

A. A Brief History of the Heart Devices

17. In 1980, termination of human arrhythmias with ICDs was reported in the New England Journal of Medicine. Thereafter, a number of devices were approved and manufactured to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms. ICDs include pacemakers as well as defibrillators. Pacemakers are used primarily to correct slow heart rates. Defibrillators detect and correct both fast and slow heart rates. Using the pacemaker and defibrillator function, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to stabilize the heart and allow for a return to an appropriate rhythm.

18. Generally, leads act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy to treat slow heart rhythms is provided through pace-sense electrodes. High voltage shocks for defibrillation are provided through high voltage conductors, also known as "leads." Typically, high voltage leads are inserted through a major vessel and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires via cables and/or conductors and are positioned in the heart, where they monitor the heartbeat and can transmit an electric shock from the ICD to abort dangerous heart rhythms or pace the heart, if necessary, into a normal rhythm.

19. Any failure that compromises the ability of the lead to sense and/or transmit electrical signals will result in a failure of the ICD to perform properly. Lead failures may include externalization of the conductors, abrasion, fractured wires/cables/conductors, insulation loss, loss of ability to capture, changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface.

B. The Regulatory Approval Process Specific to Riata Leads

20. The St. Jude Riata Leads are Class III medical devices. In May 1996, the FDA approved the original PMA for the Riata's predecessor leads (P950022). Pursuant to the applicable regulations, including but not limited to 21 C.F.R. § 814.20(b)(4)(v), Defendants' PMA application included "the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device."

21. Pursuant to 21 C.F.R. § 814.3(e), Defendants' PMA application also included all information submitted with [the application] or "incorporated by reference."

22. Defendants were also required to and did "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met" consistent with 21 C.F.R. § 820.30. Upon information and belief, Defendants maintained copies of documents that memorialize these controls and they were consulted and utilized in the manufacture of the Riata leads.

23. Pursuant to 21 C.F.R. § 820.70, Defendants were also required to and did have several process controls in place which "include[d] documented instructions, standard operating procedures, and methods that define and control the manner of production." Upon information and belief, Defendants maintained copies of documents that memorialize these process controls and they were consulted and utilized in the manufacture of the Riata leads.

24. Pursuant to 21 C.F.R. § 820.181, Defendants were required to and did maintain "device master records (DMRs)." Upon information and belief, the DMR for the Riata leads include, or refer to the location of, the following information: "(a) device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications; (b) product process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications." Upon information and belief, Defendants maintained the DMR for the Riata leads and the DMR was consulted and utilized in the manufacture of the Riata leads.

25. Pursuant to 21 C.F.R. § 820.30(j), Defendants were also required to and did maintain a "design history file (DHF)." Upon information and belief, the DHF for the Riata leads "contains or references the records necessary to demonstrate that the design was developed

in accordance with the approved design plan and the requirements of this part." Upon information and belief, Defendants maintained copies of the DHF for the Riata leads and the DHF was consulted and utilized in the manufacture of the Riata leads.

26. Pursuant to 21 C.F.R. § 820.180, Defendants were required to and did maintain "all records required by this part . . . at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections." Federal regulations, including but not limited to 21 C.F.R. § 820.180, require that such records "shall be made readily available for review and copying by FDA employee(s)."

27. Pursuant to 21 USC section 360(h), Defendants are required to be, and were, inspected by the FDA "at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter." Upon information and belief, the process controls and other documents referenced above were available to the FDA during the time of such inspections.

28. PMA Supplements are "supplemental applications to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein." 21 C.F.R. § 814.3(g).

29. From 1996 to 2002 Defendants submitted and the FDA approved 14 supplements to this original PMA. These supplements altered various aspects of the design and manufacture of the Leads. Pursuant to 21 C.F.R. § 814.3(g), these and the other Riata PMA Supplements included "all information submitted with [the PMA Supplement] or incorporated by reference therein."

30. To the extent that Defendants made "modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA," Defendants submitted such changes to the FDA in 30-day reports in accordance with 21 C.F.R. § 814.39(f). Upon information and belief, the FDA reviewed these 30-day reports.

31. On March 11, 2002, the FDA, pursuant to St. Jude Medical's application number P950022/S014, approved the Riata Series 1500 Defibrillation Lead System. This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

32. On January 22, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S015, approved an extension to the shelf-life of the Riata Leads.

33. On March 25, 2003, St. Jude Medical added two new models to the Riata Series (Model Nos. 1572 and 1582), when the FDA approved application number P950022/S016.

34. On July 1, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S017, approved the addition of a fluoroscopic marker in the helix tip and the addition of new lead lengths and modifications to the suture sleeve.

35. On April 21, 2004, the FDA approved St. Jude Medical's application number P950022/S018, a modification to the Riata defibrillation lead family to include integrated bipolar leads (Models 1560, 1561, 1562, 1590, 1591, 1592).

36. In May 2005, a series of applications for manufacturing modifications were approved by the FDA. These requests involved "dimensional changes" to the Riata Leads, changes from welding to crimping connectors, changes from manual to automated processes, as well as changes to the order of the manufacturing steps for the crimping process, and "changes to

the stylet ring and header coupling." *See* application numbers P950022/S019, P950022/S020, P950022/S021, P950022/S022, P950022/S023.

37. On June 3, 2005, the FDA approved the addition of the Riata Lead Models 7000, 7001, and 7002 under application number P950022/S024.

38. On November 4, 2005, the FDA, pursuant to St. Jude Medical's application number P950022/S025, approved the addition of six lead models with elasteon 2a lead body insulation materials to the Leads.

39. In March 2006, the FDA approved changes to the Riata Leads, including (1) modifications to the Riata ST Models 7000, 7001, and 7002 active-fixation defibrillation leads to change the geometric profile of the inner coil and addition of white pigment to the medical adhesive for shock coil backfill; (2) modifications to the Riata ST Models 7000, 7001, and 7002 leads including creation of an active-fixation integrated bipolar lead (these devices, as modified, are marketed under the trade names Riata ST Models 7010, 7011, and 7012 and are indicated for use with compatible pulse generators); and (3) modifications to the Riata ST Models 7000, 7001, and 7002 to create a passive fixation and a passive fixation integrated bipolar lead. These devices, as modified, will be marketed under the trade names Riata ST Models 7040, 7041, and 7042 (passive fixation) and Riata ST Models 7050, 7051, and 7052 (passive fixation integrated bipolar) and are indicated for use with compatible pulse generators. These changes were all included in application numbers P950022/S027 and P950022/S028.

40. On July 7, 2006, the FDA, pursuant to St. Jude Medical's application number P950022/S030, approved an overlay over the silicone lead body of the Riata ST Leads to create the new Riata ST Optim lead models 7020, 7021, 7022, 7030, 7031, 7070, and 7071.

41. In November 2006, the FDA approved St. Jude Medical's application to change the supplier for the DF-1 Boot Component of its Riata Leads (P950022/S031).

42. In December 2006, the FDA approved St. Jude Medical's application for a helix attachment modification for the Riata 1580, 1581, and 1582 leads as well as a crimp-weld coupling modification for the Riata and Riata ST lead families (P950022/S032).

43. In February 2007, the FDA approved St. Jude Medical's application to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads (P950022/S033).

44. In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads, including (1) modification to the crimp slug weld tab; (2) modification to the distal header assembly; (3) modification to the PTFE liner in the IS-1 connector leg; (4) removal of the PTFE liners in the two DF-1 connector legs; (5) addition of a DF-1 plug accessory to the lead package; (6) addition of an extra-soft stylet accessory to the lead package; (7) minor modifications to the User Manual; and (8) modified radius specification for the spring stopper component (P950022/S034). The FDA also approved an alternate supplier of the front seal component (P950022/S035), added an "alternative welding process" (P950022/S036), and added an alternate vendor of the molded connector boot for the manufacturer of Riata ST Leads (P950022/S037).

45. In June 2007, the FDA approved St. Jude Medical's application to add alternate suppliers of their connector rings and inner crimp sleeve components (P950022/S038, P950022/S039, P950022/S041, P950022/S042).

46. In October 2007, the FDA approved St. Jude Medical's application for an alternate supplier of EFTE coated cables (P950022/S043).

47. In December 2007, the FDA approved St. Jude Medical's applications to change the "shock coil backfill manufacturing process" (P950022/S046), to extend the time between plasma treatment and application of a medical adhesive (P950022/S047), and to alternate oven settings during processing of the shock coils (P950022/S048).

48. In May 2008, the FDA approved St. Jude Medical's application to add an alternate manufacturing site located at Steri-Tech, Inc., Salinas, Puerto Rico for ethylene oxide sterilization of the pacemakers, ICDs, and leads (P950022/S045).

49. In July 2008, the FDA approved St. Jude Medical's application to use a manufacturing site for the Riata Leads in Arecibo, Puerto Rico (P950022/S051).

C. FDA Inspections of Defendants' Manufacturing Facilities and Processes

50. In 2009, the FDA conducted a for-cause Quality Systems Inspection Technique ("QSIT") of Defendants' manufacturing facility in Sylmar, California. As part of this inspection, the FDA required a list of all Corrective and Preventative Action ("CAPA") and Product Improvement Requests ("PIRs") opened since 2002. Defendants provided the following PIRs regarding High Voltage Leads:

- 09-005: Helix extension retraction failure due to spring popping out of its location and getting jammed between the header coupling and stopper
- 09-001: Cable fracture under strain relief coil DF-1 leg
- 07-006: Outer coil fractures at IS-1 connector ring
- 06-014: Hypot failures in Riata ST Leads manufacturing
- 06-012: Riata coil fracture at inner coil shaft
- 06-005: Missing DF-1 crimps in HV Lead manufacturing
- 06-004: Swapped DF-1 labels in HV Lead manufacturing

- 06-003: Riata Lead with incorrect conduction paths
- 05-016: Riata integrated bipolar IS-1 connector dielectric strength improvement
- 05-009: Riata Lead abrasion
- 04-006: Insufficient crimp on RV shock coil termination ring employed on the Riata integrated bipolar leads
- 04-003: Riata perforation
- 03-006: Riata Lead cable coating abrasion
- 02-004: Riata missing weld, DF-1 connector pin

51. The inspection also revealed that Defendants had deficiencies in the handling of complaints, making Medical Device Reporting (MDR) determinations, CAPA procedures, and receiving protocols.

52. These failures violated 21 C.F.R. § 803.50(b) ("Failure to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 C.F.R. § 803.50(b)."). Specifically, the inspection report stated that St. Jude Medical's complaint files noted adverse events that St. Jude internally evaluated but did not report to the FDA.

53. As part of the inspection, the FDA interviewed Nestor Kusnierz, Director of Regulatory Compliance. According to the Report, Mr. Kusnierz is a 25 year veteran of St. Jude. His primary task is to assure the inspection runs smoothly and within the firm's regulatory procedures. Mr. Kusnierz answered questions regarding complaints and MDRs.

54. During the inspection, Mr. Kusnierz provided a spreadsheet to the FDA for all complaints for the Riata and Durata lead models dating back to 2002. This represented the time period from device approval through June 9, 2009 and totaled 8,463 complaints. For all

complaints identified as "perforation, patient," it was indicated that an MDR had been submitted. However, the FDA adverse event database contained only 3,689 MDRs from the firm for these devices during this period.

55. Prior to the inspection, 32 MDRs were identified from the adverse events database as possibly Riata perforation events, and the complaint files for these were requested and reviewed during the inspection.

56. Review of these complaint files and the associated MDRs revealed that in some cases Defendants failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 C.F.R. § 803.50(b). Specifically, the complaint files show that complainants reported perforation adverse events for the Riata and Durata devices, but these events were not reported as "perforations" in the associated MDRs submitted to the FDA by St. Jude. Additionally, perforation was not identified in the submitted Form 3540A either in the patient or device problem codes.

57. A sampling of eight complaints that were identified by Defendants as "capture anomaly," "dislodgment," or "patient discomfort" were also retrieved from the MAUDE database by device serial number for further review. Six of these reports "in fact described a suspected perforation and it could not be ruled out as possible for the other two events." As the FDA noted in its EIR, "post-market surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate and consistent."

58. Additionally, the 2009 Establishment Inspection Report noted that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by the designated individual per 21 C.F.R. § 820.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 C.F.R. § 803.50 for device

manufacturers." For example, "MDR #2017865-2008-0044 provides a manufacturer aware date and perforation event in 2003. The 3500A was submitted without explanation to FDA on January 10, 2008. Similarly, MDR #2017856-2008-00447 provides a perforation event date and manufacturer aware date in 2004, but the 3500A was also submitted without explanation to FDA on January 10, 2008."

59. The EIR continues to state that additional review of the MDRs submitted from 2007 through June 2009 found no evidence of the perforation events described in the medical or scientific literature were submitted to the FDA as required by regulations and company procedures.

60. Similarly, a 2011 report by an FDA safety officer, Jessica Paulsen, noted that Defendants' CAPAs limited the analysis to "externalized cables and [did] not include exposed cables or all other forms of abrasion, which FDA considers important contributors to the published rate of all abrasion presented in [Defendants'] November 2011 Product Performance Report (PPR)." The FDA also noted that the "published failure rate based on PPR is based only upon reported events and returned product analysis, and therefore underestimates the actual rate of occurrence."

61. The FDA also noted that Defendants' "calculation of the proportion of leads associated with inappropriate high voltage shock delivery, based on their assumptions appear[ed] to have a clerical error" and required correction.

62. The 2011 Report also notes numerous instances of underreporting and states that the terms "'externalized cable' or even 'abrasion' may not be employed when it is a contributing cause to the reporter having been unaware that externalized cable occurred. The clinical

presentation (noise, inappropriate therapy, no therapy, etc.) may be what is reported and not the diagnosis of the lead mechanical failure."

63. The FDA further noted that while Defendants reported only "1 instance of 'inappropriate high voltage shock delivery' OSEL's analysis from last January counted 71 cases of inappropriate shock, noise, and/or over sensing (out of 172 inside-out abrasion cases)." OSEL further found that "nine out of the first ten instances reviewed for these three events were referred to as 'inappropriate therapy.'" Thus, OSEL concludes, Defendants "may under-estimate the actual number of inappropriate shocks due to their limiting terminology." Additionally, the Report notes that "some literature sources reviewed by FDA have published rate information that is greater than what is included in SJM's HHE."

64. Continuing with the November 2011 report, it is noted that "OSB identified a total of 794 reports of insulation abrasion, and 116 of those reports mentioned inside-out abrasion." The report further notes that "the reports submitted by SJM to FDA concerned externalized cables and abrasion failures are not up to date."

65. MDRs are the mechanism by which the FDA receives significant medical device adverse events from manufacturers, importers, and user facilities, so that problems can be corrected quickly.

66. The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm. The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. For example, Dr. Hauser published a study in the Heart Rhythm Journal that assessed the number of deaths associated with the Riata Leads. *See* Robert G. Hauser et al.,

Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads, Heart Rhythm 9(8): 1227 (Aug. 2012). Dr. Hauser's assessment was based on his search and analysis of the MAUDE database.

67. Indeed, doctors reported abrasion problems with the Riata Leads to St. Jude. However, doctors were left with the impression that such problems were rare because St. Jude did not adequately submit this information to the FDA and/or otherwise advise the public. Specifically, an October 2012 article in the Wall Street Journal reports that physicians including Dr. Alan Cheng, director of Johns Hopkins Medicine's arrhythmia service; Dr. Samir Saba, chief of electrophysiology at the University of Pittsburgh Medical Center; and Dr. Ernest Lau at the Royal Victoria Hospital in Belfast, Ireland, had encountered abrasion in the Riata Leads between 2006 and 2009. However, when these doctors brought these incidents to the attention of St. Jude they were told by company officials and field representatives that the incidents were isolated.

68. The Wall Street Journal further reported that St. Jude had been tracking the abrasion issue for "several years" and that abrasion became the focus of an internal St. Jude audit, which examined multiple instances of that type of failure before April 2008.[1] According to the article, St. Jude's internal audit concluded in 2008 that Riata had "potentially serious insulation problems including inside-out abrasion." The audit, which had been looking broadly at insulation problems by 2006, included a special section on inside-out abrasion, which cited examples of inside-out abrasion in at least two devices extracted from patients, as well as in lab testing. The report, which did not address whether the problems resulted in injuries or deaths, said 32 of the 246 leads examined were damaged enough to inhibit lifesaving shocks. The

[1] Christopher Weaver, *St. Jude Riata Heart Device Flaws Known for Years*, Wall Street Journal (Oct. 11, 2012), available at http://online.wsj.com/news/articles/SB10000872396390444223104578036752346768278.

company had sold more than 120,000 Riata Leads in the U.S. by that time, and the risk of all abrasion-related failures appeared "remote," the audit said.

69. Accurate reporting of adverse events is essential, as it serves to notify the public that a potential problem with the device exists, and can prompt an informed person or organization to develop a solution. The FDA and others, including the public, rely upon accurate and timely reporting of adverse events. Post-market surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate, and consistent.

70. The FDA 2009 inspection also revealed that Defendants failed to follow their procedure for product design developments of the Leads.

71. As a result of these deficiencies, the FDA issued an eight-item FDA-483 report on July 8, 2009. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic Act and related Acts. FDA investigators are trained to ensure that each observation noted in a Form 483 is clear, specific, and significant.

72. Specifically, the deficiencies identified by the FDA in the Form 483 included the following:

(a) Defendants failed to include all information that was reasonably known to the manufacturer on an MDR report in violation of 21 C.F.R. § 803 et seq.

(b) Defendants failed to timely submit MDRs to the FDA and such submissions were significantly past the mandatory reporting timeframes without written explanation in violation of 21 C.F.R. § 803 et seq.

(c) Defendants failed to define the procedures for implementing corrective and preventative actions in violation of 21 C.F.R. § 820 et seq. Specifically, the Standard Operating Procedure for risk analysis failed to define the methodology for obtaining the Probability of Occurrence that is used in risk evaluations, resulting in inconsistent risk analyses.

(d) Defendants failed to review their sampling methods for adequacy of their intended use in violation of 21 C.F.R. § 820 et seq. Specifically, the procedure "Receiving Inspection Sampling Program" allows components to be accepted without receiving inspections and review of vendor certificates ("Dock to Stock method"). The procedure did not have a monitoring program for receiving components that were subject to Dock to Stock methods. As of June 23, 2009, a significant number of "critical components for defibrillation leads were Dock to Stock components." Also, the sections of "Dock to Stock General Requirements" and "Dock to Stock Part Declassification" were purged without written justifications.

(e) Defendants failed to perform design reviews at appropriate times in violation of 21 C.F.R. § 820 et seq. Specifically, Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and the Product Development Plan. Additionally, team meeting minutes were not maintained as required.

(f) Defendants failed to perform a complete risk analysis in violation of 21 C.F.R. § 820 et seq. Specifically, the Failure Mode, Effects, and Criticality Analysis (FMECA) did not include all drawings and St. Jude was unable to explain why component drawings were not evaluated for FMECA. The design FMECA analysis for components and top assembly drawings were part of the risk analysis for the Riata Leads.

(g) Defendants failed to establish procedures for the validation or verification review, and approval of design changes before their implementation in violation of 21 C.F.R. § 820 et seq. Specifically, Defendants had no written procedure describing the review and approval process of the design verification plan and report, when design changes require a verification plan.

(h) Defendants failed to resolve discrepancies noted at the completion of design verification in violation of 21 C.F.R. § 820 et seq. Specifically, the review of Quality Test Report (QTR) 1403 for Riata series 1500 shows someone who reviewed the data sheets had made a change to the specification of DC resistance on the Qualification Test Data Sheets for Composite Lead Tensile Test, but the reason for the discrepancy and reason for the change were not discussed in the QTR or meeting minutes.

73. Additionally, the 2009 Establishment Inspection Report indicated that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by the designated individual per 21 C.F.R. § 820.198(d)."

74. The FDA also noted that training on complaint handling by Defendants' field staff needed improvement. Specifically, "many products [were] returned for analysis without an associated complaint, although obtaining the reason for the explant would not be expected to be difficult for the field staff attending procedures."

75. Additionally, "review of the MDRs submitted from 2007 through June 2009 found no evidence that the events described in [medical or scientific literature] were submitted to FDA as required by regulations and company procedures."

76. The FDA also reported that Defendants' Standard Operating Procedure for Global Risk Management (SOP 4.7.2) was inadequate as it related to "clinical risk in new product development and throughout the product life cycle, and [was] inadequate in that the procedure did not establish a methodology for obtaining a Probability of Occurrence used in Risk Evaluations." Defendants' Product Improvement Requests (PIRs) demonstrated those inadequacies.

77. The FDA noted that Defendants had the required written procedure to cover design changes. However, according to the FDA, the reasons and justifications for design changes were not always properly documented.

78. As part of the inspection, the FDA also requested Defendants' World Wide Product Disposition Review Board (WWPDRB) meeting minutes, which dated back to 2006. Specifically, the WWPDRB meetings were held to "discuss issues that had a Criticality value of four or five. The meeting minutes consisted of a brief summary, list of participating members, and PowerPoint slides used for the presentation of issues."

79. During the 2009 inspection, the FDA also inquired about the design controls related to the Riata Leads, including but not limited to Conceptual Design Review Reports,

Product Development Plans, Hazard Analysis, FMECA's, Design Verification Test Reports, and Qualification Test Reports.

80. On October 17, 2012, the FDA conducted a subsequent 483 inspection of Defendants' Sylmar manufacturing facility and identified several deficiencies including failures regarding design verification, complaint handling, CPA procedures, risk analyses, inspection/ measuring/testing/calibration of equipment, document control, and employee training.

D. Manufacturing Defects with Regard to Riata Leads

81. From 2005 to 2010, St. Jude applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved many of these changes in PMA supplements. Upon information and belief, Defendants failed to manufacture the Riata Leads consistent with the specifications, requirements, federal regulations and/or the PMA thereby creating a defective product.

82. Upon information and belief, Defendants' failure to follow specifications, requirements, regulations, and/or the PMA resulted in abrasion, externalization, and/or perforation of the Riata leads. These failures include the failure to manufacture the internal conductors, or cables, at sizes consistent with the specifications, requirements, federal regulations and/or the PMA. This failure results in increased tension, bending, and/or movement of the internal conductors, or cables, within the insulation thereby causing inside-out abrasion.

83. Upon information and belief, one of these defects also includes inconsistent insulation diameters and/or thickness surrounding the electric conductors, also known as cables. On information and belief, insulation diameters and thickness are required by the specifications, requirements, federal regulations, and/or the PMA, to be consistent. Defendants' failure to manufacture insulation diameters consistent with the specifications, requirements, federal

regulations and/or the PMA results in increased tension, bending, and/or movement of the cables within the outer silicone, as well as an increased risk of abrasion at thinner insulation sites, which leads to an increased risk of device failure.

84. Additionally, St. Jude applied for and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. Upon information and belief, St. Jude failed to comply with the approved methods and/or specifications and requiremnts of curing and sterilization during the manufacture of the Leads and this failure to follow the approved cure or sterilization processes resulted in reduced tensile strength and/or degradation of the silicone insulation, which contributed to the additional tension, movement, and/or bending of the internal cables and abrasion or externalization.

85. Upon information and belief, St. Jude processed the leads in a solution which caused the cables and/or conductors to stretch and then vibrate when exposed to electrical charge through the silicone, further increasing the risk of abrasion to the leads. Upon information and belief, this process failed to follow the approved specifications, requirements, and procedures set forth in the PMA and/or federal regulations.

86. Finally, St. Jude applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and relief, a controlled, uniform degree of force was required when applying the crimp. Upon information and belief, failure to crimp with a controlled, uniform degree of force resulted in insecure crimps over the length of the Lead, which also results in increased tension, bending, and/or movement of the Lead and diminishes the integrity of the insulation—both of which result in abrasion.

87. These defects result in abrasion which occurs in situ with the insulation surrounding the cables and/or conductors. As a result, the cables may protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD. This protrusion is caused "externalization."

88. The breach of insulation and externalization of the cables and/or conductors on the Riata Leads can cause the Leads to short, and to transmit incorrect information or noise to the pacemaker/defibrillator, thereby causing it to produce unnecessary and very painful shocks of electricity, fracture, or alternatively, to fail to communicate with the pacemaker/defibrillator at which point the life-saving therapies of the device are unavailable.

89. Finally, upon information and belief, Defendants failed to adequately inspect and/or test the Leads and their component parts to ensure consistency with approved specifications, requirements, federal regulations, and/or the PMA and its Supplements.

90. Federal regulations impose standards of care on Defendants with regard to the manufacture, marketing, and sale of the Riata Leads, these regulations include but are not limited to the following: 21 C.F.R. §§ 803.10, 803.50, 803.52, 803.53, 803.56, 806, 814.20, 814.30, 814.37, 814.39, 814.80, 814.82, 814.84, 820.5, 820.20, 820.30, 820.22, 820.25, and 820.70. Upon information and belief, the Conditions of Approval for the Riata Leads also incorporate these statutes and regulations.

E. Recall of the Riata Leads

91. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the letter, St. Jude indicated that issues with defects in the insulation have been identified in the Riata Lead Models 1560, 1561, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

92. Specifically, St. Jude states that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." Additionally, St. Jude noted that the silicone used on these leads was "vulnerable to abrasion."

93. In the 2010 Dear Doctor Letter, St. Jude indicated that Lead insulation abrasion had been associated with:

(a) oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

(b) undersensing;

(c) loss of capture;

(d) changes in pacing and/or high voltage lead impedances; and

(e) inability to deliver high voltage therapy

94. Despite the dangers associated with these Leads, St. Jude did not initiate a voluntary recall of the Leads at that time. Rather, St. Jude simply noted that it was "phasing out" all Riata Lead models by the end of 2010.

95. On November 28, 2011, St. Jude Medical published a second Dear Doctor letter relating to the same set of Riata Lead models as the 2010 Dear Doctor letter.

96. The 2011 Dear Doctor letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall.

97. On December 21, 2011, the FDA reclassified St. Jude's Dear Doctor letters as a Class I Recall.

98. A Class I Recall is the most serious level of recall and is defined as a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

99. Specifically, the FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health causes, including death."

F. Physicians Expose the Riata Lead Defects

100. By September 2011, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI) was researching the FDA's MAUDE database for reported deaths related to the St. Jude Riata Leads.

101. In a manuscript sent to the *Heart Rhythm* journal in March 2012, Dr. Hauser detailed his research and conclusions comparing the failure rates of the St. Jude Riata Leads to the reported failure rates of a competitor's leads. Robert G. Hauser et al., *Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads*, Heart Rhythm 9(8): 1227 (Aug. 2012).

102. In his manuscript, Dr. Hauser indicated that the reports showed that 31% of the deaths involving the Riata Leads were lead-related whereas 8% of deaths involving a competitor's lead were lead-related. It is important to note that adverse events are often grossly underreported. *See generally* U.S. General Accounting Office, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* (Jan. 1997) (citing previous GAO findings that "less than 1 percent of the device problems occurring in hospitals were reported to the FDA" and that "the most serious the problem with the device, the less likely it was to be reported to the FDA"), *available at* http://www.gao.gov/archive/1997/he97021.pdf.

103. Additionally, Dr. Hauser noted that "[a]bnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST Lead failure, often resulting in failure to defibrillate." Robert G. Hauser et al., *Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads*, Heart Rhythm 9(8): 1227 (Aug. 2012). Finally, Dr. Hauser concluded that the Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

104. On March 8, 2012, Dr. Hauser published an article in the New England Journal of Medicine, exposing the increased harm in failing to have an accurate, active post-market reporting mechanism for medical devices and advocated for greater research and review of medical device failures in order to better protect patients. Robert G. Hauser, *Here We Go Again —Another Failure in Postmarketing Device Surveillance*, 366 New Eng. J. Med. 873, 873-75 (2012).

105. St. Jude Medical reacted to Dr. Hauser's article in what industry analysts have described as a "rare," "unprecedented," and "confounding" manner by urging the peer-reviewed journal *Heart Rhythm* to retract Dr. Hauser's article. *See* Barry Meier & Katie Thomas, *At St. Jude, Firing Back at Critics*, N.Y. Times (Apr. 11, 2012); Susan Kelly & Debra Sherman, *Heart Device Troubles Cloud St. Jude's Outlook*, Reuters (Apr. 13, 2012), available at http://www.reuters.com/article/2012/04/13/us-stjude-idUSBRE83C0ME20120413.

106. In May 2012, Dr. Hauser published additional findings regarding the Riata Lead insulation defects in the *Heart Rhythm* journal. Robert G. Hauser et al., *Riata Implantable Cardioverter-Defibrillator Lead Failure: Analysis of Explanted Leads with a Unique Insulation Defect*, Heart Rhythm (May 2012).

107. In 2012, the FDA ordered Defendants to collect clinic data related to the potential for premature insulation failure in Riata and Riata ST Leads. The FDA required Defendants to conduct three-year post-market surveillance studies, also called section 522 studies, to address concerns related to premature insulation failure and to address important questions related to follow up of affected patients.

108. In January 2012, a study published in the *Heart Rhythm* journal indicated that Defendants had recently advised that the rate of cable externalization was 24% in the Riata 8fr Leads and 9% in the Riata ST 7fr Lead—despite previous reports that such rates were only 0.63%. The article also stated that a number of studies have confirmed that Riata Leads fail more often than other brands.

V. CLAIMS FOR RELIEF

COUNT 1: STRICT LIABILITY MANUFACTURING DEFECT

109. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

110. Defendants manufactured Riata Leads such that they did not comply with the specifications and protocols set forth in the requirements, federal regulations, PMA, Supplements, and/or the conditions for approval.

111. Because Defendants did not comply with specifications and protocols set forth in the requirements, federal regulations, PMA, Supplements, and/or the conditions of approval, Defendants manufactured a defective lead. This failure results in a manufacturing defect that renders the Riata Lead unreasonably dangerous for its intended use and Plaintiff could not have anticipated the danger the defect in this product created.

112. This defect was present in the lead when it left the hands of the manufacturer and the lead was ultimately used for the purpose in the manner for which it was normally intended.

112. The manufacturing flaws in the Riata Leads were a primary and substantial cause of Plaintiff's injuries. Neither Plaintiff nor any of her treating medical professionals could have discovered the defects in time to avert her injury or prevent her damages.

113. As a direct and proximate result of Defendants' failure to properly manufacture the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT 2: NEGLIGENT MANUFACTURING

114. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

115. Defendants have a duty to manufacture the Riata Leads consistent with the specifications, requirements, federal regulations, PMA, and/or conditions of approval. Defendants breached this duty. Plaintiff's lead possesses a manufacturing defect because the actual manufacture of the Leads differs from the specifications set forth in the requirements, PMA and/or conditions of approval.

116. Because Defendants did not comply with specifications and protocols set forth in the requirements, federal regulations, PMA, Supplements, and/or the conditions of approval, Defendants violated their duties to Plaintiff and caused her to be injured.

117. The manufacturing flaws in the Riata Leads were a primary and substantial cause of Plaintiff's injuries. Neither Plaintiff nor any of her treating medical professionals could have discovered the flaws in the Riata Leads in time to avert her injury or prevent her damages.

118. As a direct and proximate result of Defendants' failure to properly manufacture the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT 3: FAILURE TO WARN

119. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

120. Defendants have a continuing duty to monitor the Riata Leads post-approval and to discover and report to the FDA any complaints about product performance and any health consequences of which they are aware that may be attributable to the product.

121. Defendants also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Leads.

122. Defendants breached these duties by failing to provide timely and adequate post-approval reports regarding safety hazards and/or potential defects associated with the Leads. As set forth above, many of the untimely and/or inadequate reports regarding safety hazards concerned abrasion-related defects, including but not limited to externalization of cables, perforation, inappropriate therapy, sensing problems, and inside-out abrasion.

123. Had Defendants properly and timely reported adverse events to the FDA as required by federal law, information regarding the risks and hazards of the Leads would have reached Plaintiff's treating medical professionals in time to prevent or reduce Plaintiff's injuries.

124. As a direct and proximate cause of Defendants' breaches of duty, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

A. For economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial.

B. For compensatory damages according to proof.

C. For declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Defendants' wrongdoing.

D. For disgorgement of profits.

E. For attorney fees and costs.

F. For prejudgment interest and costs of suit.

G. For such other and further relief as this Court may deem just and proper.

VII. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: January 22, 2014

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